



Atty. Dkt. No. 029318-0978

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicants: H. William BOSCH et al.  
Title: NOVEL GLIPIZIDE COMPOSITIONS  
Appl. No.: 10/701,064  
Filing Date: 11/05/2003  
Examiner: Unassigned  
Art Unit: 1615

**INFORMATION DISCLOSURE STATEMENT**  
**UNDER 37 CFR §1.56**

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Commissioner for Patents  
PO Box 1450  
Alexandria, Virginia 22313-1450

Sir:

Submitted herewith on Form PTO/SB/08 is a listing of documents known to Applicants in order to comply with Applicants' duty of disclosure pursuant to 37 CFR §1.56. A copy of each listed document, except as noted below, is being submitted to comply with the provisions of 37 CFR §1.97 and §1.98.

The USPTO has waived the requirement under 37 CFR 1.98(a)(2)(i) to submit copies of U.S. patents and U.S. patent application publications when citing and submitting an Information Disclosure Statements in a patent application filed after June 30, 2003 and in an international application that has entered the national stage under 37 USC §371 after June 30, 2003. Accordingly, copies of these types of documents are not being supplied in connection with this application. Reference is being made to Pre-OG Notice from Office of Patent Legal Administration dated July 25, 2003, *Information Disclosure Statements May Be Filed Without Copies of U.S. Patents and Published Applications in Patent Applications filed after June 30, 2003.*

Documents A132-A145 and A149-A151 were cited by or submitted to the U.S. PTO in parent application Serial Nos. 09/337, 675; filed 06/22/1999, and 10/276,400, filed 01/15/2003. As provided in 37 CFR §1.98(d), copies of these documents are not being provided since they were previously submitted to the United States Patent & Trademark Office in the above-identified parent applications.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

#### **TIMING OF THE DISCLOSURE**

The listed documents are being submitted in compliance with 37 CFR §1.97(b), before the mailing date of the first Office Action on the merits.

#### **RELEVANCE OF EACH DOCUMENT**

All of the documents are in English.

Applicants respectfully request that any listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

Respectfully submitted,

Date May 3, 2004

By Michele M. Simkin

FOLEY & LARDNER LLP  
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Michele M. Simkin  
Attorney for Applicants  
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Substitute for form 1449B/PTO

INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 5

## Complete if Known

Application Number	10/701,064
Filing Date	11/05/2003
First Named Inventor	H. William Bosch
Group Art Unit	1615
Examiner Name	Unassigned
Attorney Docket Number	029318-0978

## U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			
	A1	3,669,966		AMBROGI ET AL.	06/13/1972	
	A2	4,178,695		ERBEIA	12/18/1979	
	A3	4,540,602		MOTOYAMA ET AL.	09/10/1985	
	A4	4,616,047		LAFON	10/07/1986	
	A5	4,642,903		DAVIES	02/17/1987	
	A6	4,708,868		BRICKL ET AL.	11/24/1987	
	A7	4,727,077		HAGA ET AL.	02/23/1988	
	A8	4,783,484		VIOLANTE ET AL.	11/08/1988	
	A9	4,826,689		VIOLANTO ET AL.	05/02/1989	
	A10	4,851,421		IWASAKI ET AL.	07/25/1989	
	A11	4,904,668		KONDO ET AL.	02/27/1990	
	A12	4,983,605		KONDO ET AL.	01/08/1991	
	A13	4,997,454		VIOLANTE ET AL.	03/05/1991	
	A14	5,002,952		KONDO ET AL.	03/26/1991	
	A15	5,073,374		MCCARTY	12/17/1991	
	A16	5,098,907		KONDO ET AL.	03/24/1992	
	A17	5,110,605		ACHARYA	05/1992	
	A18	5,112,616		MCCARTY	05/12/1992	
	A19	5,145,684		LIVERSIDGE ET AL.	09/08/1992	
	A20	5,178,878		WEHLING ET AL.	01/12/1993	
	A21	5,188,825		ILES ET AL.	02/23/1993	
	A22	5,215,758		KRISHNAMURTHY	06/1993	
	A23	5,219,574		WEHLING ET AL.	06/15/1993	
	A24	5,223,264		WEHLING ET AL.	06/29/1993	
	A25	5,260,478		BACON ET AL.	11/1993	
	A26	5,264,610		BACON	11/1993	
	A27	5,264,213		SHIBAHARA ET AL.	11/23/1993	
	A28	5,298,262		NA ET AL.	03/29/1994	
	A29	5,300,739		BITTAR	04/1994	
	A30	5,302,401		LIVERSIDGE ET AL.	04/12/1994	
	A31	5,318,767		LIVERSIDGE ET AL.	06/07/1994	
	A32	5,326,552		NA ET AL.	07/05/1994	
	A33	5,328,404		BACON	07/12/1994	
	A34	5,336,507		NA ET AL.	08/09/1994	
	A35	5,340,564		ILLIG ET AL.	08/23/1994	
	A36	5,346,702		NA ET AL.	09/13/1994	
	A37	5,349,957		YUDELSON	09/27/1994	
	A38	5,352,459		HOLLISTER ET AL.	10/04/1994	
	A39	5,384,124		COURTEILLE ET AL.	01/24/1995	
	A40	5,399,363		LIVERSIDGE ET AL.	03/21/1995	
	A41	5,401,492		KELLAR ET AL.	03/28/1995	

Examiner  
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<sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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				Group Art Unit	1615
				Examiner Name	Unassigned
Sheet	2	of	5	Attorney Docket Number	029318-0978

U.S. PATENT DOCUMENTS					
		U.S. Patent Document			
	A42	5,401,513		WEHLING ET AL.	03/28/1995
	A43	5,429,824		JUNE	07/04/1995
	A44	5,446,464		FELDLE	08/29/1995
	A45	5,447,710		NA ET AL.	09/05/1995
	A46	5,451,393		LIVERSIDGE ET AL.	09/19/1995
	A47	5,464,632		COUSIN ET AL.	11/07/1995
	A48	5,466,440		RUDDY ET AL.	11/14/1995
	A49	5,470,583		NA ET AL.	11/28/1995
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	A53	5,503,846		WEHLING ET AL.	04/02/1996
	A54	5,510,118		BOSCH ET AL.	04/23/1996
	A55	5,518,187		BRUNO ET AL.	05/21/1996
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	A58	5,525,328		BACON ET AL.	06/11/1996
	A59	5,534,270		DE CASTRO	07/09/1996
	A60	5,543,133		SWANSON ET AL.	08/06/1996
	A61	5,552,160		LIVERSIDGE ET AL.	09/03/1996
	A62	5,560,931		EICKHOFF ET AL.	10/01/1996
	A63	5,560,932		BAGCHI ET AL.	10/01/1996
	A64	5,565,188		WONG ET AL.	10/15/1996
	A65	5,567,439		ALLEN JR. ET AL.	09/15/1998
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	A70	5,573,783		DESIENO ET AL.	11/12/1996
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	A74	5,587,143		WONG	12/24/1996
	A75	5,587,172		CHERUKURI ET AL.	12/24/1996
	A76	5,587,180		ALLEN JR. ET AL.	12/24/1996
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	A83	5,628,981		LIVERSIDGE ET AL.	05/13/1997
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Examiner Signature	Date Considered
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				First Named Inventor	H. William Bosch
				Group Art Unit	1615
				Examiner Name	Unassigned
Sheet	3	of	5	Attorney Docket Number	029318-0978

U.S. PATENT DOCUMENTS					
		U.S. Patent Document			
	A85	5,635,210		ALLEN JR. ET AL.	06/03/1997
	A86	5,639,475		BETTMAN ET AL.	07/17/1997
	A87	5,641,515		RAMTOOLA	06/1997
	A88	5,643,552		ILLIG	07/01/1997
	A89	5,662,883		BAGCHI ET AL.	09/02/1997
	A90	5,665,331		BAGCHI ET AL.	09/09/1997
	A91	5,709,886		BETTMAN ET AL.	01/20/1998
	A92	5,718,388		CZEKAI ET AL.	02/17/1998
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	A94	5,741,522		VIOLANTE ET AL.	04/21/1998
	A95	5,747,001		WIEDMANN ET AL.	05/05/1998
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	A97	5,807,576		ALLEN JR. ET AL.	09/15/1998
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	A100	5,811,388		FRIEND ET AL.	09/1998
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	A103	5,811,425		WOODS ET AL.	09/1998
	A104	5,827,541		YARWOOD ET AL.	10/27/1998
	A105	5,834,025		DE GARAVILLA ET AL.	11/10/1998
	A106	5,851,553		MYERS ET AL.	12/22/1998
	A107	5,862,999		CZEKAI ET AL.	01/26/1999
	A108	5,866,163		MYERS ET AL.	02/02/1999
	A109	5,869,098		MISRA ET AL.	02/09/1999
	A110	5,871,781		MYERS ET AL.	02/16/1999
	A111	6,045,829		LIVERSIDGE ET AL.	04/04/2000
	A112	6,068,858		LIVERSIDGE ET AL.	05/30/2000
	A113	6,153,225		LEE ET AL.	11/28/2000
	A114	6,165,506		JAIN ET AL.	12/26/2000
	A115	6,221,400	B1	LIVERSIDGE ET AL.	04/24/2001
	A116	6,264,922	B1	WOOD ET AL.	07/24/2001
	A117	6,267,989	B1	LIVERSIDGE ET AL.	07/31/2001
	A118	6,270,806	B1	LIVERSIDGE ET AL.	08/07/2001
	A119	6,316,029	B1	JAIN ET AL.	11/13/2001
	A120	6,375,986	B1	RYDE ET AL.	04/23/2002
	A121	6,428,814	B1	BOSCH	08/06/2002
	A122	6,431,478	B1	REED ET AL.	08/13/2002
	A123	6,432,381	B1	LIVERSIDGE ET AL.	08/13/2002
	A124	6,464,988	B1	GIDWANI ET AL.	10/15/2002
	A125	6,555,139	B2	SHARMA	04/29/2003
	A126	6,579,895	B1	KARIM ET AL.	06/17/2003
	A127	6,583,180	B2	LINK ET AL.	06/24/2003

Examiner Signature		Date Considered	
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				Group Art Unit	1615
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Sheet	4	of	5	Attorney Docket Number	029318-0978

U.S. PATENT DOCUMENTS						
	U.S. Patent Document					
	A128	6,592,903	B2	RYDE ET AL.	07/15/2003	
	A129	6,604,698	B2	VERHOFF ET AL.	08/12/2003	
	A130	2002/0012675	A1	JAIN ET AL.	01/31/2002	

FOREIGN PATENT DOCUMENTS								
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Documents	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
	A131	WO	98/098565		ELAN PHARMA INTERNATIONAL LIMITED	12/12/2002		
	A132	WO	91/13612		BEECHAM GROUP PLC	09/1991		
	A133	EP	0 275 796		CENT. NAT. RECH. SCIENT. FR	07/1988		
	A134	WO	98/35666		NANOSYSTEMS LLC	08/20/1998		
	A135	WO	98/07414		RES TRIANGLE PHARM LTD.	02/26/1998		
	A136	WO	93/10760		ALFATEC PHARMA GMBH ET AL.	06/10/1993		
	A137	WO	93/10767		ALFATEC PHARMA GMBH	06/10/1993		
	A138	EP	0 262 560	A2	ISHIHARA MINING & CHEMICAL CO. ET AL.	09/22/1987		
	A139	WO	98/46215	A1	CIMA LABS INC.	10/22/1998		
	A140	EP	0 636 365	A1	MCNEIL-PPC INC.	02/01/1995		
	A141	WO	96/13251	A1	SCHERER	05/09/1996		
	A142	WO	96/24339	A1	NANOSYSTEMS	08/15/1996		
	A143	WO	96/24336	A1	NANOSYSTEMS	08/15/1996		
	A144	WO	93/25190	A1	STERLING WINTHROP	12/23/1993		
	A145	WO	01/45674	A1	COCENSYS	06/28/2001		

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.		T <sup>6</sup>
	A146	Physcians' Desk Reference, 57 <sup>th</sup> edition, pp. 2606-2607,		
	A147	Wahlin-Boll et al., <i>Clin. Pharmacokinet.</i> , Jul.-Aug.: 363-72 (1982).		

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	A148	Lindahl et al., "Characterization of Fluids from the Stomach and Proximal Jejunum in Men and Women", <i>Pharmaceutical Research</i> , Vol. 14, No. 4, 1997, pp. 497-502.		
	A149	KONDO ET AL., "Improved Oral Absorption of Enteric Coprecipitates of a Poorly Soluble Drug", <i>J. Pharm. Sciences</i> , 83(4): 566-570 (1994).		
	A150	KONDO ET AL., "Improved Oral Absorption of a Poorly Water-Soluble Drug HO-221, by Wet-Bead Milling Particles in Submicron Region", <i>Chem. Pharm. Bull.</i> , 41(4): 737-740 (1993).		
	A151	KONDO ET AL., "Pharmacokinetics of a Micronized, Poorly Water Soluble Drug, HO-221 in Experimental Animals", <i>Biol. Pharm. Bull.</i> 16(8): 796-800, (1993).		

Examiner Signature		Date Considered	
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